IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., FERRING B.V., and FERRING INTERNATIONAL CENTER S.A.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-479 (GMS)
SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, and ALLERGAN, INC.,	)	
Defendants.	)	

SERENITY'S AND REPRISE'S OPENING BRIEF IN SUPPORT OF THEIR MOTION TO DISMISS OR, IN THE ALTERNATIVE, TO TRANSFER

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Pursuant to Fed. R. Civ. P. 12(b)(1), (2), and (6), Defendants Serenity Pharmaceuticals, LLC ("Serenity") and Reprise Biopharmaceutics, LLC ("Reprise") (collectively, "Defendants" or "Serenity") respectfully submit this opening brief in support of their motion to dismiss the complaint for declaratory judgment (D.I. 1), filed on April 28, 2017 by Ferring Pharmaceuticals Inc., Ferring B.V., and Ferring International Center S.A. (collectively, "Ferring"), or, in the alternative, to transfer venue pursuant to 28 U.S.C. § 1404(a).

I. INTRODUCTION

Ferring's action for declaratory judgment should be dismissed in its entirety under Fed. R. Civ. P. 12(b)(1) because Ferring fails to identify any case or controversy that warrants immediate attention from the Court. Instead, Ferring seeks an advisory ruling that its unapproved (and currently unapprovable) NOCDURNA product will not infringe three of Defendants' patents -- U.S. Patent Nos. 7,405,203; 7,579,321; and 7,799,761 (collectively, "the patents in suit") -- and that those patents are invalid and/or unenforceable. The FDA has expressly rejected Ferring's applications to approve NOCDURNA on three separate occasions, and there is no timeline for ultimate approval. Accordingly, Ferring's assertion that it "anticipates further review of [its clinical data] by the FDA beginning in the third quarter of 2017, with ***the potential*** for a favorable outcome as early as the first half of 2018" is, put charitably, wishful thinking. (D.I. 1, ¶ 73.)

Indeed, the public record concerning FDA review of Ferring's NOCDURNA product demonstrates that Ferring's product will not be approved any time soon -- if ever -- because the FDA has identified serious problems both with the toxicity and efficacy of Ferring's proposed product and its clinical trial data. (*See, e.g.*, Ex. 6; Ex. 9.[1]) And, based on the FDA's comments,

[1] Citations to "Ex. __" refer to Exhibits 1-14 attached to the Declaration of Christopher J. Harnett, Esq., filed with this brief.

Ferring may need to reformulate its product and conduct new, properly designed clinical trials before any possible FDA approval. That could take years. Accordingly, Ferring cannot establish declaratory judgment jurisdiction.

Even if a case or controversy with the requisite immediacy did exist here -- which it does not -- Ferring should not have filed its declaratory judgment complaint in this Court. The proper venue for any action between Ferring and Serenity involving the three patents in suit would be the U.S. District Court for the Southern District of New York ("SDNY") where, for the past five years, Judge Robert W. Sweet has been presiding over a litigation between Ferring and the Defendants involving the very same patents that Ferring challenges in its DJ complaint. In the course of that lengthy, ongoing SDNY litigation, Judge Sweet has developed extensive knowledge about the parties, the patents in suit, and the underlying technology.

Beyond the lack of case or controversy and Ferring's inappropriate selection of venue, Ferring's DJ complaint suffers from additional defects. For example, in asserting that the three patents in suit are unenforceable, Ferring does not -- and cannot possibly -- satisfy the heightened requirements for pleading inequitable conduct and, accordingly, its unenforceability defense should be dismissed. Ferring's inequitable conduct charge centers on Dr. Seymour Fein's assertion that he is the correct inventor of the patents in suit. Ferring, however, acknowledges nowhere in its submissions to this Court that Judge Sweet has already ruled that Ferring cannot properly challenge Dr. Fein's inventorship claim and that Dr. Fein reasonably relied on Ferring's conduct to reinforce his belief that he is the true and correct inventor of those patents.[2]

[2] Another defect in Ferring's DJ Complaint is that Ferring does not (and cannot) plead sufficient facts to establish that this Court has personal jurisdiction over Reprise -- the owner of the patents in suit. Accordingly, its complaint should be dismissed as to Reprise under Rule 12(b)(2) as well.

II. NATURE AND STAGE OF THE PROCEEDINGS

Ferring's complaint for declaratory judgment arises from a dispute that is already the subject of the ongoing SDNY litigation referenced above -- *Ferring v. Allergan*, C.A. No. 12-2650 (S.D.N.Y.). That dispute pertains to inventions made by Dr. Seymour Fein concerning desmopressin, a synthetic hormone that is used to treat disorders involving excessive urine production. One such disorder is nocturia, which disproportionately affects people over the age of 50 and is characterized by the need to awaken repeatedly during the night to urinate. Dr. Fein discovered that surprisingly low doses of desmopressin can be used to treat nocturia effectively and, because of the low dose, the incidence of an adverse side effect, hyponatremia (depressed sodium levels in the blood) can be significantly reduced or eliminated. In recognition of Dr. Fein's discoveries, the USPTO granted the three patents in suit.

In 2008, Dr. Fein assigned his rights to the applications that ultimately issued as those patents to Reprise -- an organization in which Dr. Fein and Dr. Ron Nardi are principals. Dr. Fein is also the Chief Medical Officer of Serenity, a company that was formed in 2007 to develop desmopressin products that are protected by the patents in suit. In 2010, Serenity and Reprise entered into an agreement with Allergan to assist with the development of "SER120," a low-dose desmopressin formulation that is administered intranasally. On March 3, 2017, the FDA granted its approval to SER120 (under the trade name "NOCTIVA"). NOCTIVA is the first product ever approved by the FDA for the treatment of nocturia. (Ex. 1.)

On March 6, 2017, following the FDA's approval of NOCTIVA, Serenity announced that Allergan had exercised its contractual option to withdraw from the development agreement with Serenity and Reprise. As a consequence, Serenity is now financially responsible for further development and commercialization of the NOCTIVA product and is actively seeking a partner to assist in those efforts. (Ex. 2.)

Approximately five years earlier, Ferring filed its lawsuit in the SDNY naming Allergan, Serenity, Reprise, Dr. Fein, and Dr. Nardi as defendants (collectively, "the SDNY defendants"). In its SDNY complaint, Ferring asserted fourteen state law claims as well as three federal claims under 35 U.S.C. § 256 -- all of which were premised on Ferring's allegation that Ferring had inventorship rights in Dr. Fein's three patents in suit. In that regard, Ferring contended that Dr. Fein's patents included "significant inventive contributions" of Ferring's own employees. (Ex. 3 ¶ 103.) Ferring also sought, *inter alia*, to disgorge the $43 million that Serenity and Reprise received from Allergan in return for access to the patent rights. (*Id.* ¶¶ 330, 335.)

The SDNY defendants denied all of the charges set forth in Ferring's complaint and filed a counterclaim under 35 U.S.C. § 256, asserting that Dr. Fein was either the sole or, alternatively, a joint inventor of two patents assigned to Ferring -- U.S. Patent Nos. 7,560,429 and 7,947,654 (collectively, "the Ferring Patents"). (Ex. 4 ¶¶ 69-94.)

After several years of litigation, having previously ruled against Ferring on all fourteen of its state law causes of action, Judge Sweet ruled that Ferring could not properly challenge Dr. Fein's inventorship of the '203, '321, and '761 patents. Specifically, on September 22, 2015, Judge Sweet granted the SDNY Defendants' motion for summary judgment dismissing Ferring's federal inventorship claims on the grounds of equitable estoppel. (Ex. 5.) On January 7, 2016, Judge Sweet denied Ferring's summary judgment motion in part seeking to dismiss the SDNY Defendants' federal inventorship counterclaims. Trial on the SDNY defendants' counterclaims to add Dr. Fein as an inventor on Ferring's patents is expected to commence later this year.

In sum, during five years of litigation in the SDNY, Ferring asserted that: (1) Ferring was the rightful owner of the three patents in suit; (2) those patents include "significant" and "inventive" contributions of Ferring scientists; and (3) Ferring was entitled to recover the value

of (and proceeds from) those patents, which exceeded $43 million. (Ex. 3 ¶¶ 103, 330, 335.) Then, after Judge Sweet issued a series of rulings providing that Ferring could not properly challenge Serenity's ownership of the patents in suit, Ferring filed its DJ complaint in this Court ***asserting now that the patents in suit are actually worthless*** because they are: (1) invalid under 35 U.S.C. § 102(e); (2) invalid under 35 U.S.C. § 102(f); (3) invalid for lack of enablement; (4) invalid for lack of written description; (5) invalid for indefiniteness; and (6) unenforceable for alleged inequitable conduct. And, the timing of Ferring's Delaware DJ action coincides with Serenity's efforts to attract a commercial partner to bring NOCTIVA to market following Allergan's withdrawal from the product development agreement.

III. SUMMARY OF ARGUMENT

1. ***Ferring's declaratory judgment complaint should be dismissed because Ferring cannot identify a case or controversy of sufficient immediacy.*** The public record demonstrates that the FDA has repeatedly refused to approve Ferring's NOCDURNA product because of serious deficiencies in its clinical data and, accordingly, as currently formulated, ***NOCDURNA may never receive FDA approval***. Nevertheless, in an effort to invoke DJ jurisdiction, Ferring has inaccurately characterized NOCDURNA's regulatory review status. For example, Ferring asserts that it has filed a Citizen Petition to "express concern" that the FDA "'may be poised to apply its safety and efficacy standards'" inconsistently between Defendants approved NOCTIVA product and Ferring's unapproved NOCDURNA product. (D.I. 1, ¶ 63). Ferring, however, does not acknowledge the FDA's March 3, 2017 response to that concern: "***We disagree***. FDA applied the same statutory approval standard to both applications." (Ex. 6, at 8 n.17.)

Ferring also alleges that there is "potential for favorable [regulatory] outcome by the first half of 2018" because, supposedly "the FDA agreed to reconsider Ferring's clinical trial data to reassess the clinical benefit of NOCDURNA." (D.I. 1, ¶¶ 66, 73). That is an overstatement --

the FDA merely stated, "If Ferring believes that it can re-analyze its existing data in a manner that can support a clinically meaningful benefit for NOCDURNA, Ferring can meet with [the appropriate FDA division] to discuss this." (Ex. 6, at 10.) Tellingly, the FDA continued, "FDA is unable to conclude whether any new analyses submitted will lead to a different regulatory outcome for NOCDURNA until it has reviewed such data." (*Id.* at 10 n.20.) Indeed, the public record shows that the FDA rejected Ferring's test data because Ferring designed its clinical trials so as to significantly understate the potential incidence of an adverse event, hyponatremia. (*Id.* at 11.) In its DJ complaint, Ferring itself acknowledged the seriousness of hyponatremia: "Symptoms associated with hyponatremia include nausea, headache and lethargy, but in severe cases it can result in seizures, coma, and death." (D.I. 1, ¶ 51.) And, based on the public record of the FDA's comments, Ferring may need to reformulate its product to obtain approval. Accordingly, NOCDURNA remains unapproved and there is no certainty when -- if ever -- it will be approved. In such circumstances, where product approval is not imminent and, indeed, is highly speculative, Judge Andrews has ruled that Declaratory Judgment jurisdiction does not exist. *See, e.g., Clarus Therapeutics Inc. v. Lipocine, Inc.*, C.A. No. 15-1004 (RGA), 2016 WL 5868065 (D. Del. Oct. 6, 2016).

2. ***If Ferring could properly invoke declaratory judgment jurisdiction -- which it cannot -- the appropriate venue for the case is the SDNY, where Judge Sweet has spent five years on a closely related litigation between the same parties involving the same three patents in suit.*** In the course of the SDNY litigation, which is still ongoing, Judge Sweet has considered dozens of submissions from the parties including detailed technical declarations from the inventors and experts and has issued numerous written opinions. Accordingly, since April 2012, Judge Sweet has become deeply knowledgeable about the parties, the development of the

underlying technology, and the patents. In considering transfer, a key "public interest" factor is "practical considerations that could make trial easy, expeditious, or inexpensive." In evaluating that factor, the Delaware District Court has determined that, "[i]f a related case involves (1) the same parties, (2) related or similar technologies for the judge to become familiar with, and (3) a common field of prior art, then these practical considerations weigh in favor of transfer." *Abbott Labs. v. Roxane Labs., Inc.*, C.A. No. 12-457 (RGA) (CJB), 2013 WL 2322770, at *23 (D. Del. May 28, 2013).

3. ***Additional "public interest" factors and "private interest" factors also militate in favor of transfer***. Beyond Judge Sweet's extensive familiarity with the parties, patents, technology, and other relevant issues, additional public interest factors would favor transfer of this case to the SDNY in the event that it is not dismissed for lack of case or controversy. For example, the "relative administrative difficulty in the two fora resulting from court congestion" favors transfer. At present, there are more than 700 patent cases pending in the District of Delaware, and the burden of that case load is particularly acute given Senior Judge Robinson's imminent retirement and the uncertainty surrounding the timing of the filling of her vacancy. It makes little sense for an already overburdened Court to replicate the extensive work previously undertaken by the SDNY's Judge Sweet.

The relevant "private interest" factors also confirm that Ferring's inappropriate choice of forum should be given no deference. For example, Reprise -- the owner of the patents in suit -- is not a Delaware resident: Reprise is organized under the laws of New York and has its principle place of business within the Southern District.[3] Likewise, Serenity has offices within

[3] Ferring's averment at ¶ 24 of its DJ complaint that "[t]his Court has personal jurisdiction over Reprise at least because Reprise has continuous and systematic contacts with Delaware corporate entities within Delaware, including Serenity and Allergan" is insufficient to establish personal jurisdiction over Reprise -- the owner of the patents in suit. *See infra* Section V.D.

the Southern District and Serenity's CEO (Dr. Herschkowitz), the inventor of the patents in suit (Dr. Fein), and other key witnesses (such as Dr. Nardi) reside in New York City or the surrounding suburbs. Even Ferring has its U.S. headquarters in Parsippany, NJ which is substantially closer to New York than to Wilmington. And, New York, with major international airports nearby -- would be far more convenient for Ferring witnesses traveling from the Netherlands and Switzerland. Under such circumstances transfer is strongly favored. *See, e.g.*, *Wacoh Co. v. Kionix Inc.*, 845 F. Supp. 2d 597, 605 (D. Del. 2012); *Semcon Tech., LLC v. Intel Corp.*, C.A. No. 12-531 (RGA), 2013 U.S. Dist. LEXIS 2596, at *22-23 (D. Del. Jan. 8, 2013).

IV. STATEMENT OF FACTS

A. Ferring's Continuing Inability To Secure FDA Approval for NOCDURNA

On June 22, 2009, Ferring submitted NDA No. 022517 to the FDA, seeking approval of its proposed NOCDURNA product for the treatment of nocturia in adult patients. (D.I. 1, ¶ 61.) To date, that NDA has not been approved and there is no timeline for expected approval.

1. FDA Has Rejected Ferring's Application Three Times

In April 2010, the FDA issued its first Complete Response Letter directed to NOCDURNA. (Ex. 7.) In that letter, the FDA identified deficiencies in Ferring's supporting data and advised Ferring that it "must conduct a clinical trial" before the proposed product could be approved. (*Id.* at 1.) Ferring then proceeded to conduct two clinical trials and submitted the results to the FDA on July 30, 2012. After considering Ferring's submission, the FDA issued a second Complete Response Letter on January 30, 2013. (Ex. 8.) In that second letter, the FDA advised Ferring that it was "not convinced" that NOCDURNA was safe and effective and requested additional clinical trials. (Ex. 6, at 3; *see also* Ex. 8.)

In response to the FDA's January 30, 2013 Complete Response Letter, Ferring filed an appeal in which it argued that, contrary to Agency findings, it had demonstrated the effectiveness

and safety of NOCDURNA. (Ex. 6, at 3.) Thereafter, the Agency convened an Advisory Committee meeting to discuss the safety and efficacy data for that product. That committee concluded that Ferring's data was insufficient to establish clinically meaningful effects of NOCDURNA. (*Id.*) Consequently, on January 30, 2015, the FDA issued its third Complete Response Letter, stating that Ferring had provided "insufficient evidence" to support approval of NOCDURNA, and reiterated the need for a new clinical trial. (Ex. 9, at 1.)

2. Ferring's Unsuccessful Citizen Petition

On November 29, 2016, following the denial of its appeal, Ferring filed a Citizen Petition. In that petition, Ferring repeated its arguments about the supposed approvability of NOCDURNA. Ferring also asked the FDA to withhold approval for Serenity's NOCTIVA product. (Ex. 10.) Specifically, Ferring complained that the FDA "may be poised to apply its safety and efficacy standards . . . different[ly]" to Ferring's NOCDURNA product and Serenity's NOCTIVA product. (*Id.* at 1.) In that regard, Ferring asked that the FDA "refrain from approving Serenity's NDA or any other application for a desmopressin product to treat nocturia" until the FDA establishes: (1) "a consistent interpretation of the standard for effectiveness, particularly for purposes of determining whether the effect of the drug is clinically meaningful;" and (2) "a consistent interpretation of the standard for safety, particularly actions needed to mitigate the risk of hyponatremia." (*Id.* at 2-3.)

On March 3, 2017, the FDA denied Ferring's Citizen Petition. In response to Ferring's complaint that the FDA was "poised to apply its safety and efficacy standards differently" to NOCTURNA and NOCTIVA, the FDA stated:

> We disagree. FDA applied the same statutory approval standard to both applications. The ultimate decision about the approvability of NOCDURNA and SER120 [NOCTIVA] is based on the Agency's assessment of the evidence presented in each application under the standard. (Ex. 6, at 8 n.17.)

The FDA also denied Ferring's request to withhold approval of Serenity's NDA for NOCTIVA. Indeed, the FDA approved Serenity's product on the same day. (*Id.* at 14.)

In the FDA's Citizen Petition response, Dr. Janet Woodcock (the Director of FDA's Center For Drug Evaluation and Research) drew a stark comparison between the clinical data that Serenity submitted for its approved NOCTIVA product and the data that Ferring submitted in connection with its rejected NOCDURNA product. Specifically, Dr. Woodcock observed that Serenity's clinical trials were closer to the "real world" use of desmopressin. (*Id.* at 11 n.24.)

In that regard, Dr. Woodcock pointed out fundamental problems with Ferring's clinical study design in connection with hyponatremia -- a serious and potentially lethal adverse event characterized by low blood concentration of sodium. Dr. Woodcock commented that the risk of hyponatremia "increases with advancing age" and noted that Ferring enrolled patients as young as 18 years of age in its desmopressin trials. Serenity, in contrast, properly studied NOCTIVA using patients aged 50 and above. (*Id.* at 11.)

Dr. Woodcock and the FDA pointed out other problems with Ferring's data as well. Specifically, Ferring instructed the patients in its NOCDURNA trials to restrict their intake of fluid, alcohol, and caffeine. Those instructions resulted in a potentially significant understatement of the incidence of hyponatremia. Consequently, the FDA observed disqualifying problems with Ferring's clinical trial design:

> [T]he Serenity trials had features that provided more experience with the expected patient population and more assurance that the treatment results are closer to what could be expected with "real world" use of the drug. ***Unlike the NOCDURNA clinical trials, the SER120 clinical trials included an older patient populations and had no restriction on fluid, alcohol, or caffeine intake.*** Fluid restriction in the NOCDURNA trials may have helped to mitigate the risk of hyponatremia in the trials, but fluid restriction may be difficult to maintain with real-world use of the drug. ***Therefore, the SER120 trials included additional systemic stressors that were absent from the NOCDURNA trials.*** (*Id.* at 11 n.24.)

The FDA's comparative evaluation of Serenity's clinical trial design and Ferring's clinical trial design drew attention from the trade press. For example, one article summarized the FDA's conclusions as follows:

> Serenity's Noctiva and Ferring's NOCDURNA both use desmopressin to treat nocturia, but NOCDURNA has racked up three complete response letters while Noctiva was approved on the first try. US FDA explains how trial design and secondary endpoints influenced its decision in its denial of a Ferring citizen petition. *A Tale of Two Desmopressins* (March 7, 2017), *available at* https://pink.pharmamedtechbi.com/PS120176/A-Tale-Of-Two-Desmopressins-Trial-Design-Gave-Noctiva-Advantage-Over-Nocdurna-US-FDA-Says; *see also* Ex. 11.[4]

3. Ferring's Upcoming Discussions With The FDA

In the March 3, 2017 response to Ferring's Citizen Petition, the FDA advised Ferring of its right to request a follow-up meeting with the appropriate FDA personnel to discuss the status of Ferring's clinical data. Specifically, the FDA stated:

> When the Agency issued the January 30, 2015 CR letter, the Agency did not believe that Ferring's existing data alone provided sufficient evidence of a clinically meaningful benefit to support approval without additional clinical data. If Ferring believes it can re-analyze its existing data in a manner that can support a clinically meaningful benefit for NOCDURNA, Ferring can meet with DBRUP to discuss this. (Ex. 6, at 10.)

Meetings between the FDA and NDA applicants such as Ferring to discuss rejected clinical data are encouraged by governing FDA regulations. 21 C.F.R. 314.103(c)(2) provides:

> When scientific or medical disputes arise . . . applicants should discuss the matter directly with the responsible reviewing officials. If necessary, ***applicants may request a meeting*** with the appropriate reviewing officials . . . . ***FDA will make every attempt to grant requests for meetings*** that involve important issues and that can be scheduled at mutually convenient times.

Although the FDA reminded Ferring of its option to schedule a meeting if Ferring believed that "it can re-analyze" its NOCDURNA data (Ex. 6, at 10), it also advised Ferring that:

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[4] Unlike Ferring's proposed NOCDURNA products, which are orally-administered sublingual tablets, the SER120 nasal spray treatments allow targeted delivery of extremely low doses of desmopressin, while simultaneously offering improved efficacy and safety profiles due to increased bioavailability and decreased inter-patient variability in drug absorption. (Ex. 14, at 7-8.)

"FDA is unable to conclude whether any new analyses submitted will lead to a different regulatory outcome for NOCDURNA until it has reviewed such data" (Ex. 6, at 10 n.20).

B. Judge Sweet Has Extensive Experience With The Parties, The Patents In Suit And The Underlying Technology

In the ongoing SDNY litigation, Judge Sweet, to date, has presided over at least five motion hearings and issued seven detailed written opinions exceeding 200 pages in the aggregate. In so doing, Judge Sweet has considered numerous technical declarations and expert reports. He has also considered hundreds of pages of exhibits including the three patents in suit, patent prosecution documents, technical literature, and transcript excerpts from the depositions of fact and expert witnesses. (*See, e.g.*, Ex. 5; Ex. 12; Ex. 13.)

During the past five years, Judge Sweet has become knowledgeable about the parties and their interrelationships including: the former association between Drs. Fein and Nardi with Ferring; the efforts of Drs. Fein and Nardi to establish Serenity and Reprise; and the partnership between Serenity/Reprise and Allergan. Simultaneously, Judge Sweet attained a detailed understanding of the desmopressin drug and Dr. Fein's inventive work on developing low dose formulations of desmopressin to treat nocturia. He also has become familiar with Serenity's FDA-approved NOCTIVA product and Ferring's unapproved NOCDURNA product.

And, Judge Sweet has had the opportunity to study the three patents in suit as well as other patents and publications concerning desmopressin formulations, including "prior art" that Ferring identifies in connection with its premature claim for invalidity under 35 USC Sections 102(e) and (f). (*Compare* D.I. 1, ¶¶ 32-34, 80-85, *with, e.g.*, Ex. 5, at 4-5; Ex. 12, at 5-6.)

In a detailed decision issued on March 19, 2013, Judge Sweet explained why Ferring's 14 state law claims directed to ownership of the patents in suit should be dismissed pursuant to Rule 12(b)(6), Fed. R. Civ. P. *Ferring B.V. v. Allergan, Inc.*, 932 F. Supp. 2d 493 (S.D.N.Y. 2013).

Then, on September 22, 2015, Judge Sweet issued his decision dismissing Ferring's federal inventorship claims on the grounds of equitable estoppel. In that regard, Judge Sweet observed:

> Dr. Fein relied upon Ferring's inaction by spending several years commercializing his invention, including research and investments by both himself and the entities he helped form, Reprise and Serenity. He also asserted unchallenged ownership over the inventions to the companies that acquired his intellectual property based on Ferring's misleading silence. (Ex. 5, at 29.)

V. ARGUMENT

A. The Court Does Not Have Jurisdiction Over Ferring's DJ Claims

Article III of the U.S. Constitution limits federal jurisdiction to suits that address "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Aetna Life Ins. Co. of Hartford, Conn. v. Haworth*, 300 U.S. 277, 241 (1937). The requirement of an "actual controversy" under the Declaratory Judgment Act is the same as that of Article III justiciability. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007). Accordingly, a Court properly exercises subject matter jurisdiction over an action for declaratory judgment only if "the facts alleged, under all the circumstances, show that there is a substantial controversy between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id*. at 126-127.

1. The Controlling Authorities Provide That There Is No Justiciable Controversy Here

In the patent context, courts are reluctant to find "sufficient immediacy and reality" where there is no present act of infringement. *See Benitec Australia, Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346–47 (Fed. Cir. 2007); *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1280 (Fed. Cir. 2014). When the product at issue is a pharmaceutical, this reluctance is even more pronounced in circumstances "when, and even whether, the FDA will approve" the potentially infringing product is purely "speculative." *Clarus*, 2016 WL 5868065, at *3. Although FDA

approval is not always required for a potential infringer to seek declaratory relief (for example, in the context of an ANDA matter), "absence of FDA approval is evidence that the dispute between the parties is neither real nor immediate." *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, C.A. No. 05-590 (GMS), 2006 WL 2375035, at *3 n.3 (D. Del. Aug. 16, 2006). Moreover, "the greater the length of" time between the filing of the complaint and the beginning of the potentially infringing activity, "the more likely the case lacks the requisite immediacy." *Sierra Applied Sciences Inc. v. Advanced Energy Industries, Inc.*, 363 F.3d 1361, 1378-79 (Fed. Cir. 2004); *see also Clarus*, 2016 WL 5868065, at *3. Finally, "[e]ven assuming an actual controversy, the exercise of a court's jurisdiction over a declaratory judgment action is discretionary." *Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1526 (Fed. Cir. 1992).

2. Ferring's Assertions About Favorable FDA Review Are Inconsistent With The Public Record

Notwithstanding three different Complete Response Letters from the FDA rejecting Ferring's NOCDURNA clinical data and the denial of Ferring's Citizen Petition, Ferring contends in its DJ complaint that it "anticipates further review of the data by the FDA beginning in the third quarter of 2017, with the potential for a favorable outcome as early as the first half of 2018." (D.I. 1, ¶ 73.) The only "support" that Ferring presents for its "potential for favorable outcome" claim is that the FDA agreed to a meeting to give Ferring the opportunity to argue, if it can, that its clinical data may be "re-analyze[d]." But the mere fact that the FDA has agreed to a meeting with Ferring is irrelevant -- the applicable Federal Regulations provide that the FDA should conduct meetings with an NDA applicant whenever possible. (*Supra* Section IV.A.3.)

Beyond that, in the March 3, 2017 Citizen Petition response, the FDA ***already*** cast doubt on Ferring's "potential for favorable outcome" claim. Indeed, the FDA stated that it is "unable to conclude whether any new analyses submitted will lead to a different regulatory outcome for

NOCDURNA until it has reviewed such data." (Ex. 6, at 10 n.20.) And, the data in question is ***the very same data*** that the FDA has repeatedly rejected -- and criticized -- because Ferring designed its clinical trials to mask the incidence of a serious adverse event by enrolling inappropriately young patients and by issuing instructions that were divorced from "real world" use of the drug. Because the flawed patient selection and flawed instructions pervaded Ferring's clinical studies, simply "re-analyz[ing]" the data from those studies will be meaningless.

Consequently, it seems far more likely that the FDA will again reiterate its demand for new clinical trials (which will take a considerable amount of time with absolutely no guarantee of success) and far less likely that there will be a "favorable outcome as early as the first quarter of 2018." And, as stated above, Ferring may very well need to reformulate and retest its product to receive FDA approval. (Ex. 6, at 3-4; *id.* at 10 n.20.) This reformulation and retesting process would take years, and could change the entire legal analysis of infringement.

Accordingly, there is no immediate case or controversy here. In *Clarus*, Judge Andrews found that "there is no indication that either FDA approval or . . . entry into the market is imminent" and concluded "[b]ecause the declaratory judgment complaint is based on future events that lack immediacy, the Court does not have jurisdiction to hear this case." 2016 WL 5868065, at *3. Ferring is certainly no closer to FDA approval or entry into the market than the plaintiff in *Clarus* and its complaint should be dismissed for the same reason.

3. Ferring's Assertions About "Threats" From Serenity Are Misleading

Ferring alleges that Serenity has "engaged in a course of conduct that shows an immediate preparedness and willingness to enforce their patent rights against Ferring." (D.I. 1, ¶ 69). That allegation is diversionary. For example, as supposed evidence of "threat" from Serenity, Ferring presents selective quotes from Serenity that pertain to European Patent Office

proceedings. (*Id.* ¶ 70). But in Europe, Ferring actually has an approved product; here there is a great likelihood that the FDA will ***never*** approve NOCDURNA, in which case there will be no possibility of an infringement action.

Serenity is presently focused on finding a commercial partner to bring its approved NOCTIVA to market. Serenity should not be forced to spend its limited resources defending against Ferring's invalidity and unenforceability attacks on Serenity's patents when the likelihood of Ferring receiving FDA approval any time soon is remote, and, in fact, it may never happen. As such, there is no immediate case or controversy.

B. Even If Subject Matter Jurisdiction Existed Here, Transfer Is Warranted

As Serenity details below, even if an immediate case or controversy existed in connection with Ferring's NOCDURNA product -- which it does not -- the controlling law and the facts presented here overwhelmingly favor transfer of this case to the SDNY. Indeed, given Judge Sweet's familiarity with the parties, patents, and technology, it would be an appropriate exercise of this Court's discretion to either address the question of subject matter jurisdiction itself or to permit Judge Sweet to address it.

1. SDNY Would Be The Proper Venue

It is well established that an action should be transferred to another district, pursuant to 28 U.S.C. § 1404(a), if it could have been brought in that district and the balance of convenience factors weigh in favor of transfer. *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 883 (3d Cir. 1995). "[S]ection 1404(a) was intended to vest district courts with broad discretion to determine . . . whether convenience and fairness considerations weigh in favor of transfer." *Id.* (citing *Stewart Organization, Inc. v. Ricoh Corp.*, 487 U.S. 22, 30-31 (1988)).

In undertaking the transfer inquiry, courts consider whether a balancing of certain private and public interests weights in favor of transfer. *See id.* at 879. Private interest factors that

courts consider include the parties' respective forum preference. *Id.* Although the plaintiff's choice of forum is given deference, it "should not be afforded substantial weight" if it is "arbitrary, irrational, or selected to impede the efficient and convenient progress of a case." *Abbott Labs v. Roxane Labs. Inc*., C.A. No. 12-457 (RGA) (CJB), 2013 WL 2322770 at *18 (citing *Affymetrix, Inc. v. Synteni, Inc*., 28 F. Supp. 2d 192, 200 (D. Del. 1998)).[5]

The public interest analysis includes practical considerations -- such as a judge's familiarity with the facts underlying the litigation -- that could make the trial easy, expeditious, or inexpensive. *See Jumara*, 55 F.3d at 879-80; *Abbott*, 2013 WL 2322770 at *23. As such, "a related case involv[ing] (1) the same parties, (2) related or similar technologies of the judge to become familiar with, and (3) a common field of prior art . . . weigh[s] in favor of transfer." *Abbott*, 2013 WL 2322770 at *23; *see also In re DVI Inc*., C.A. No. 03-12656 (MFW), 2004 WL 1498593, at *3 (D. Del. June 23, 2004). The relative administrative difficulty in the two fora resulting from court congestion is also factored into the analysis. *Jumara*, 55 F.3d at 879.

2. The Facts Of This Case Support Transfer

Ferring's own actions confirm that the present action "could have been brought" in the SDNY. When Ferring sued Serenity and Reprise about the ownership of the very same patents at issue here, Ferring invoked the jurisdiction of the SDNY. (Ex. 3.)

This Court should flatly reject any argument presented by Ferring that its "choice of forum" should be afforded deference. Ferring's April 2012 SDNY complaint recites a litany of facts pertaining to those public and private interest factors and is replete with averments that the

[5] Apart from plaintiff's choice of forum, other private interest factors include: (1) the defendant's preference; (2) whether the claim arose elsewhere; (3) the convenience of the parties as indicated by their relative physical and financial condition; (4) the convenience of the witnesses -- but only to the extent that the witnesses may actually be unavailable for trial in one of the fora; and (5) the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum.) *Jumara*, 55 F.3d at 879. Here, those remaining factors either weigh in favor of transfer or are neutral. (*See supra* Section III.)

SDNY is the appropriate forum to: (1) address disputes between Ferring and Serenity/Reprise; and (2) consider issues pertaining to the three patents in suit. When all is said and done, Ferring should not be permitted to burden this Court with its obvious attempt at forum shopping simply because Ferring is dissatisfied with rulings issued against it by Judge Sweet in the SDNY.

C. Ferring's Inequitable Conduct Claim Does Not Satisfy Applicable Pleading Requirements Which Is An Additional Reason For Dismissal

According to Ferring, the patents in suit are unenforceable because, during prosecution, Dr. Fein and his counsel supposedly engaged in inequitable conduct by presenting intentional misrepresentations and omissions regarding the inventorship and priority of the claimed subject matter. (*See* D.I. 1, ¶¶ 106-115). Because Ferring's allegations do not satisfy the requisite standards for pleading an inequitable conduct charge, that charge should be dismissed for failure to state a claim on which relief can be granted under Fed. R. Civ. P. 12(b)(6).

The U.S. Supreme Court has made clear that: "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation omitted). A well-pleaded complaint requires "more than a sheer possibility that a defendant has acted unlawfully." *Id*. Accordingly, a claim for inequitable conduct must "satisfy the heightened pleading requirement of [Rule] 9(b)." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1316 (Fed. Cir. 2009).

A finding of inequitable conduct requires "that the applicant misrepresented or omitted material information with the specific intent to deceive the [USPTO]." *Therasense, Inc.v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). Thus, the pleading "must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen*, 575 F.3d at 1328. Moreover, to successfully plead intent, the pleading must include sufficient allegations of underlying facts "from which a

Court ***may reasonably infer*** that a specific individual (1) knew of the material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Id.* at 1328-29; *see also Softview LLC v. Apple Inc.*, C.A. No. 10-389 (LPS), 2011 WL 4571793, at *1 (D. Del. Sept. 30, 2011).

Here, Ferring's allegations fail the plausibility and heightened pleading requirements because: (1) Ferring does not state any underlying facts pertinent to several key alleged misrepresentations; and (2) Ferring's "knowledge" and "intent" allegations cannot support a reasonable inference that Dr. Fein intended to mislead the PTO -- particularly in light of Judge Sweet's decisions in the SDNY case.

Ferring contends that Dr. Fein falsely claimed sole inventorship of the patents in suit and, in consultation with his counsel[6] failed to disclose the existence of an inventorship dispute to the PTO. (D.I. 1, ¶¶ 108-113). Ferring, however, does not -- and cannot -- come to terms with SDNY's ruling that Dr. Fein properly relied on Ferring's conduct in believing that his inventorship of the patents in suit was not in dispute. (Ex. 5.) In fact, Ferring filed the SDNY action in 2012, ***after*** the patents in suit issued, claiming ownership and inventorship of the very same patents that it now seeks to invalidate. Consequently, any identifiable inventorship dispute arose after the issuance of the patents, which, by itself, guts Ferring's inequitable conduct claim.

Beyond that, in dismissing Ferring's inventorship claims, Judge Sweet determined that the parties' dealings and communications throughout 2003 -- coupled with Ferring's subsequent inaction for over seven years -- gave rise to equitable estoppel. In that regard, Judge Sweet found that Dr. Fein reasonably believed that the subject matter of the patents in suit was, in fact, his invention. *Id.* at pp. 29-30. In light of this ruling, Ferring cannot plausibly allege (and this

[6] Ferring repeatedly alleges that the misrepresentations and omissions were made by "Dr. Fein and his counsel," without identifying the specific individuals at the law firm that prosecuted the patent application.

Court cannot reasonably infer) that there was an inventorship dispute during the prosecution of the patents in suit, and that Dr. Fein knew of the alleged omissions to the PTO regarding inventorship or intended to mislead the PTO.[7]

D. Ferring's Failure To Plead Facts Sufficient To Establish Personal Jurisdiction Over Reprise Is Yet Another Reason For Dismissal

As Ferring acknowledges in its complaint, Reprise -- the owner of the patents in suit -- is a New York corporation with its principal place of business in New City, NY. (D.I. 1, ¶ 7.) Ferring's claims that "[t]his Court has personal jurisdiction over Reprise at least because Reprise has continuous and systematic contacts with Delaware corporate entities within Delaware, including Serenity and Allergan." (*Id.* ¶ 24.) Defendants are aware of no authority finding such assertions sufficient to establish personal jurisdiction; in fact, controlling Supreme Court precedent suggests otherwise. *See Daimler AG v. Bauman*, 134 S. Ct. 746, 760 (2014) (limiting general jurisdiction based on "continuous and systematic contacts" to corporation's place of incorporation and its principal place of business).

VI. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss, or in the alternative, to transfer, should be granted.

[7] Ferring's allegations regarding Dr. Fein and his prosecution counsel's allegedly false priority claim also fail. (*See* D.I. 1, ¶ 114.) Without providing any specifics, Ferring merely states "[o]n information and belief" that Dr. Fein and his counsel claimed priority to a Great Britain patent application with an intent to deceive the PTO. Those allegations do not provide any underlying facts upon which the Court might reasonably infer knowledge of the alleged false priority claim, or a specific intent to deceive the PTO.

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June 9, 2017

CERTIFICATE OF SERVICE

I hereby certify that on June 9, 2017, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 9, 2017, upon the following in the manner indicated:

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